

## **MREDI Quarterly Report: SYNERGISTIC IMPROVEMENT IN THE DIAGNOSIS & TREATMENT OF MENTAL ILLNESS, DEMENTIA, & CHRONIC PAIN**

This progress report is organized “by project” for each of the Center’s four funded projects.

**Objective 1:** Combine EEG and fNIRS for clinical diagnostic development for anxiety and depressive disorder.

### *Overview:*

Objective 1 remains approximately 60 days behind schedule as the result of an arising need to renegotiate the prices of the equipment being purchased with our Montana-based business partner (Neuralynx, Inc.). However, substantial progress has been made since the previous update.

TechEn, Inc. and Neuralynx, Inc. have worked together to finish construction of the combined EEG-fNIRS system. Training on the EEG system is occurring during the week of March 21st and training on the fNIRS system is scheduled to take place March 28th - 30th.

A project coordinator has been identified (January 2016) and has worked to assemble recruitment materials and created digital copies of study measures for computerized administration.

An offer has been made to a graduate student research assistant for compensated involvement in the study.

The training of research assistants on the fNIRS system will continue for the next several weeks, until high-quality data are reliably collected. Following this, recruitment of research participants will begin. Undergraduate research staff have been recruited to allow for data collection during the summer months.

### *Equipment purchased:*

Equipment has been purchased from Neuralynx, Inc. and TechEn, Inc. as described in the research proposal.

### *Progress towards milestones (since previous update):*

- Equipment has been ordered from the Montana-based business (Neuralynx, Inc.) and external business partner (TechEn, Inc.) identified in the proposal. The construction of this equipment is complete and has been delivered to Montana State University.
- Setups and trainings on the combined EEG/fNIRS system are scheduled and will be complete before April 1, 2016.
- A project coordinator has been hire and has begun work on the project.
- Recruitment materials have been prepared.
- The Research space in which the study will take place has been identified.

### *Total amount of expenditures by report date:*

- Neuralynx, Inc.: \$65,000 for EEG setup and caps
- TechEn, Inc: \$53,600 for fNIRS setup

- Project coordinator salary: \$502.50
- Project coordinator benefits: \$19.35

**Objective 2:** Conduct a breakthrough study on the use of Deep TMS for Alzheimer's Disease (AD) in order to improve the lives of Montana families affected by AD and make Western Montana Mental Health Center in Butte a treatment destination for patients from across Montana.

*Overview:*

As with Objective 1 that is also using the EEG-fNIRS technology, Objective 2 remains approximately 60 days behind schedule due to previously described contracting delays for equipment. However, substantial progress has been made since the previous update. Contracting is on track for completion for the TMS device by the end of March.

As noted for project 1, TechEn, Inc. and Neuralynx, Inc. have finished construction of the combined EEG-fNIRS system. Training on the EEG-fNIRS and TMS systems is planned in April once the study coordinator's hire is complete. We are planning to complete training of staff and initiate enrollment of subjects in April or May, 2016.

*Hirings:*

We have completed contracting for our Alzheimer's disease clinical research consultant and our EEG consultant (Lauren Ethridge, Ph.D.). Contracting for our TMS expert co-investigator (Sambit Mohapatra, Ph.D., University of Montana) is nearly complete. Hiring is still underway for the research study coordinator that will work in Butte, but four candidates have been identified and a hire is expected to be completed by the time of IRB approval in early April.

*Equipment purchased:*

Purchases have been completed with Neuralynx, Inc. and TechEn, Inc. and equipment will be delivered within the next few days. Contracting is underway for TMS device and as previously planned will be completed by the end of March.

*Progress towards milestones:*

- All equipment will be purchased by the end of March and delivered by the time of IRB approval.
- All hires are in place except for study coordinator for Butte, who will be hired and in place by time of IRB approval.
- IRB application was submitted and was reviewed by the committee on 3/24. We have received a request from the IRB to make multiple modest changes to the protocol and informed consent, which we anticipate will be approved within a few weeks.
- Initial recruitment planning is completed and will be refined once study coordinator is hired.
- Western Montana Mental Health Center is ready for delivery of equipment and to begin training once study coordinator is hired.

*Total amount of expenditures by report date:*

- Corrections to last report: The Purchasing Orders for Neuralynx and TechEn were initiated at the time of the last report. Amounts had not been expended. The expenditures have now begun as listed below.
- Neuralynx, Inc. : \$58,412 for EEG setup
- TechEn, Inc.: \$100,237.50 for fNIRS setup
- Payroll of Research Managing Director & Business Manager: \$8,990.46
- Travel expenditures: \$14.69

**Objective 3:** Establish efficacy and safety in a non-human primate model to facilitate clinical candidate selection of non-opioid therapeutic agents for acute and chronic pain, common correlates of anxiety, depression and neurodegeneration.

*Overview:*

Dr. Yeomans has continued with test runs of the primate model in conjunction with MSU's ARC staff, which are progressing well. Project progress remains ahead of projected timelines.

*Hirings:*

Potential hires specifically supporting these activities are being evaluated for this calendar.

*Equipment purchased:*

Cardiac/respiratory monitor at \$3,000.

*Progress towards milestones:*

- Selection of a non-opioid drug candidates for initiation in IND enabling studies has been successfully completed and ongoing testing is in progress.

*Total amount of expenditures by report date:*

- Total expenditures to date are \$51K

**Objective 4:** Investigate the ability of the Youth Aware of Mental Health Program (YAM) to prevent suicidal behaviors and improve mental health in freshmen high school students in Montana.

*Overview:*

Objective 4 is entirely on track for timelines.

*Hirings:*

Research staff hiring, including part-time support of a research managing director and research business manager have been completed. A YAM study coordinator has been hired and will begin work in May of 2016. Training for the facilitators is set for April 4-8. We have communicated with several private technology vendor and received quotes, with a plan to complete contracting with a tech vendor by the end of April.

*Equipment purchased:*

None.

*Progress towards milestones:*

- We continue to have the support of the Office of Public Instruction and DPHHS for the proposed study.
- Have obtained support (or strong interest) to conduct the study now in 11 high schools (Browning general and alternative schools, Kalispell and Glacier High Schools, Butte Alternative High School, and Custer County District High School-Miles City, Terry High School, Lodge Grass High School, and Helena and Capital High Schools, and Gardiner High School). The grant included 8-10 schools, so we likely have completed our recruitment of schools for the study.
- We are still in the process for developing a bid for the technology contractor, but have identified several potential companies.
- We have set a YAM facilitator training for April 4-8 and are planning to begin delivering YAM in the fall of 2016 to at least 8-10 high schools.

*Total amount of expenditures by report date:*

- Travel & School Recruitment Costs: \$3,002.14
- Supplies: \$77.43
- Payroll of Research Managing Director & Business Manager: \$12,237.15